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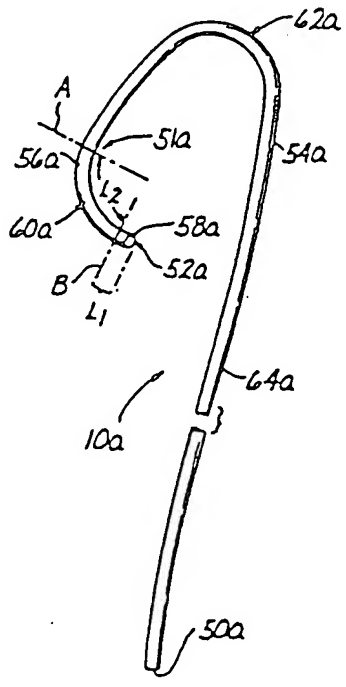
(57) Abstract

A flexible cardiovascular catheter (10a) at least a first proximal section, (54a) a second intermediate section (56a) which is more flexible than the first proximal section and a third distal section (58a) which is more flexible than the second intermediate section. The second intermediate section (56a) is of constant rigidity along its entire length. Curvatures may be formed in the catheter to facilitate insertion and positioning of the catheter in desired blood vessels. Presently preferred embodiments of the catheter are particularly usable as coronary artery guiding catheters or coronary angiography catheters.



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CARDIOVASCULAR CATHETER HAVING DISCRETE REGIONS OF VARYING FLEXIBILITY

Field of the Invention

The present invention relates generally to medical equipment and more particularly to an improved cardiovascular catheter having at least three regions of varying flexibility.

Background of the Invention

Various types of flexible cardiovascular catheters are well known in the art. The various types of flexible cardiovascular catheters of the prior art include catheters which are specifically sized and configured for percutaneous transluminal insertion into the coronary arteries. Such coronary artery catheters include "coronary angiography catheters" used for infusion of radiopaque contrast media directly into a coronary artery as well as "coronary guiding catheters" used to guide the passage of a second catheter or device (e.g. a balloon angioplasty catheter) into a coronary artery.

It is highly desirable that coronary artery catheters (e.g. angiography catheters, guiding catheters) be sized, configured and constructed so as to avoid iatrogenic trauma to the vascular intima during insertion of the catheter and to promote the safety and efficacy of the diagnostic and/or therapeutic procedures being conducted.

The prior art includes numerous coronary artery catheters which are configured with preformed bends formed

therein to facilitate insertion and safe residence of such catheters within the coronary arteries. Also, the prior art includes various preformed guidewires which are specifically shaped for easy insertion into a desired coronary artery and which are subsequently usable to guide a flexible angiocatheter to a desired location within such coronary artery.

Some examples of coronary artery catheters of the prior art are included in the following United States patents: 4,739,768 (Engelson); 4,385,635 (Ruiz); 4,813,930 (Elliott); 4,759,748 (Reed); 4,817,613 (Jaraczewski et al.); 4,586,923 (Gould et al.); and 4,636,346 (Gold et al.). Additionally, flexible guidewires usable for guidance and placement for guide catheters/angioplasty catheters are described in the following United States patents: 4,921,482 (Hammerslag et al.); and 4,884,579 (Engelson).

In addition to the incorporation of preformed bends or curves to facilitate advancement and placement of the catheters and/or guidewires in specific regions of the vascular anatomy, some of the catheters and guidewires of the prior art have also incorporated flexible distal tips to prevent or minimize the likelihood of trauma to the luminal surfaces of the blood vessels as the catheter or guidewire is being advanced therethrough.

Additionally, some catheters and/or guidewires of the prior art have incorporated region(s) of varying flexibility along their lengths so as to facilitate ease of

passage and/or placement of the catheter and/or guidewire within a specific region of the vasculature.

In particular, United States Patent No. 4,385,635 (Ruiz) describes an angiographic catheter having a soft flexible distal tip, a main reinforced length and an intermediate zone which extends between the distal tip and the main reinforced length. The main reinforced length of the RUIZ catheter incorporates an inner reinforcing tube of polyamide material. The tube of polyamide material also extends through the intermediate section, however, the mass of polyamide material is tapered or gradually lessened as it passes through the intermediate zone, thereby resulting in a gradual decrease in rigidity through the intermediate zone. Thus, the intermediate zone of the RUIZ catheter is of gradually changing flexibility and is not of uniform flexibility throughout its entire length.

Also, at least one cardiovascular catheter of the prior art incorporates a braided stainless steel member within a proximal portion of the catheter body as well as a flexible distal tip disposed on the distal end of the catheter body. The incorporation of the braided member within the proximal region of the catheter body is for the purpose of reinforcing that region of the catheter body in a manner that will prevent torsional flexing so that any torque applied to the extreme proximal end of the catheter will be transmitted through the length of the catheter body wherein such braided reinforcement member is disposed.

Although some cardiovascular catheters of the prior art have incorporated preformed curves, and regions of varied flexibility for the purpose of facilitating and steering and placement of the catheter, none of these prior art devices are found to be optimal for all coronary artery catheterization applications. Accordingly, there remains a need in the art for an improved cardiovascular catheter which may be transluminally inserted into a coronary artery with minimal manipulation and minimal likelihood of trauma to the luminal surfaces of the blood vessels and tissues surrounding the coronary ostia.

Summary of the Invention

The present invention overcomes some or all of the above-mentioned deficiencies of the prior art by providing a cardiovascular catheter which has at least three separate sections or regions of differing flexibility. Said at least three sections or regions comprise: (a) a first (proximal) section, (b) a second (intermediate) section of consistent rigidity along its entire length, the rigidity of the second intermediate section being less than that of the first proximal section, and (c) a third (distal) tip section, the rigidity of said distal tip section being less than that of the second intermediate section.

In accordance with one embodiment of the invention, the catheter body is of substantially constant size and mass along its entire length and the differences in flexibility between the first (proximal), second (intermediate) and third (distal) sections of the catheter

are accomplished by variations in material type. Materials of different flexibility are used so that the flexibility of the catheter will vary from section to section. In embodiments wherein the regionalized variations in flexibility between the first, second and third sections of the catheter are brought about by variations in material type, the materials of which each section is constructed will be selected based on the flexural properties and/or surface hardness of materials. In such catheters, it is typical that the proximal section of the catheter be formed of a material having a flexural modulus at 37°C (i.e. according to ASTM Method No. D-790) of 20,000 - 40,000 psi and preferably about 30,000 psi. The material of which the second intermediate section of the catheter is formed will typically have a flexural modulus at 37°C of 15,000 - 35,000 psi and preferably about 25,000 psi. The material of which the third distal tip section of the catheter is formed will typically have a flexural modulus at 37°C of 2,000 - 10,000 psi and preferably about 5,000 psi.

In accordance with a further aspect of the invention, two or more adjacent sections of the catheter may be formed of the same material, or materials having substantially the same flexural properties and the differences in flexibility of the catheter from section to section may be accomplished by decreasing the mass or cross-sectional diameter of the catheter, in specific section(s) thereof, thus, resulting in differing flexibility of the catheter from section to section. For example, the first (proximal) section and

second (intermediate) section of the catheter may be formed of the same material having the same flexural physical properties but the outer diameter of the catheter in the second intermediate section may be reduced or lessened relative to the outer diameter of the first (proximal) section, thereby causing the second (intermediate) section of the catheter to be of less mass (e.g. thinner walled) and, thus, more flexible and less rigid than the first (proximal) section thereof. In such embodiment, the inner diameter of the catheter lumen may be constant throughout its length thereby providing a smooth constant diameter lumen while the outer diameter of the catheter varies to accomplish the desired variations in flexibility of the catheter, from section to section thereof. Also, in such embodiment, the third (distal) tip section of the catheter may be of any size or diameter as the first (proximal) section of the catheter but is formed of a material which is more flexible and less rigid than the material of which the first (proximal) and second (intermediate) sections of the catheter are formed.

In accordance with a still further aspect of the invention, the difference in flexibility between the first, second and third sections of the catheter may be accomplished by a combination of (a) variations in material type or density between sections of the catheter and (b) variations in mass or cross-sectional diameter between sections of the catheter.

In accordance with a still further aspect of the invention, the relative lengths of the second (intermediate) and third (distal tip) sections may be specifically sized to correspond to the specific anatomical regions of the human vasculature in which the catheter is intended to be positioned (e.g. the aortic arch and coronary ostium). For example, in an adult coronary angiography catheter or coronary guiding catheter intended to be placed in a coronary artery, the length of the third (distal tip) section may be 0.1 - 0.5 centimeters and preferably about 0.3 centimeters while the length of the second (intermediate) section may be 1.0 - 10.0 centimeters and preferably about 4 centimeters. The first (proximal) section of the catheter, and any additional sections of the catheter which are proximal to the third section (i.e. a fourth section, a fifth section, etc.) may also be sized to correspond to the specific region(s) of the vasculature in which such sections of the catheter are intended to be placed. For example, in an adult coronary angiography catheter or coronary guiding catheter of the present invention, the third (proximal) section is typically about 80-100 centimeters in length such that the total length of the catheter will be approximately 100 centimeters.

In accordance with a still further aspect of the invention, one or more preformed bends or curves may be formed in the catheter to facilitate passage of the catheter through specific blood vessels and/or to facilitate residence of the catheter within a specific

anatomical region of the human vasculature without undue stress or pressure being applied to the walls of the blood vessels wherein the catheter resides. For example, in an adult coronary angiography catheter or coronary guiding catheter of the present invention, a "secondary" curve may be formed in a portion of the first (proximal) section of the catheter to substantially conform that portion of the catheter to the shape of the aortic arch. Also, a "primary" curve may be formed in the second (intermediate) distal tip of the catheter and serves to direct the distal tip of the catheter to facilitate insertion of the distal tip into the intended coronary artery.

Further aspects of the invention will become apparent to those skilled in the art upon reading the following detailed description of preferred embodiments and the accompanying drawings.

Brief Description of the Drawings

FIG. 1 is a plan view of a typical transluminal coronary artery balloon angioplasty system of the prior art;

FIG. 2 is a perspective view of a left coronary artery catheter of the present invention wherein the proximal, intermediate and distal regions of the catheter have substantially equivalent diameters but are each formed of different materials having differing flexural properties;

FIG. 2a is a perspective view of a left coronary artery catheter of the present invention wherein the intermediate region of the catheter is formed of the same

material as the proximal portion but is of smaller diameter than the proximal portion so as to be more flexible than the proximal portion thereof;

FIG. 3 is an illustration of a human being having a coronary artery catheter of the present invention inserted through the femoral artery and advanced through the aorta to an operative position wherein the distal tip of the catheter is in the left coronary artery;

FIG. 4 is a cross-sectional view of the heart and aorta having a left coronary artery catheter of the present invention operatively positioned therein;

FIG. 5 is a perspective view of a right coronary artery catheter of the present invention wherein the proximal, intermediate and distal regions of the catheter have substantially equivalent diameters but are formed of different materials having different flexural properties; and

FIG. 6 is a cross-sectional view of the aortic arch and associated blood vessels wherein a right coronary artery catheter of the present invention has been operatively positioned.

Detailed Description of Preferred Embodiments

The following descriptions and the accompanying drawings are provided for purposes of illustrating and describing presently preferred embodiments of the invention and are not intended to limit the scope of the invention.

Referring to the drawings, Figure 1 is a schematic showing of a typical transluminal balloon angioplasty

system of the prior art. As shown, the typical balloon angioplasty system comprises a flexible coronary guiding catheter 10 which is percutaneously inserted into an artery (e.g. the axial or femoral artery) and subsequently advanced to a point where the distal tip of the guiding catheter 10 resides within the ostium of a target coronary artery. Thereafter, a thin flexible guidewire 12 is advanced through the lumen of the guiding catheter 10 such that the distal end of the guidewire 12 advances out of and beyond the distal tip of the guiding catheter 10, reaching a point adjacent or within the offending stenotic lesion. Thereafter, a balloon angioplasty catheter 16 is advanced over the guidewire to a point where the angioplasty balloon 14 resides adjacent the offending stenotic lesion. The angioplasty balloon 14 is then repetitively inflated and deflated to bring about dilation of the stenotic lesion, thereby opening the previously occluded coronary artery.

Constant pressure ports 32 and 34 are provided for passing constant pressure saline solution through the guiding catheter 10 and balloon catheter 16 respectively. The passage of such constant pressure saline solution through the guiding catheter 10 and balloon catheter 16 is intended to prevent backflow of blood through the catheter and to permit periodic flushing of the catheter.

Attendant syringes 28 an 30 are mounted on manifolds 24, 26 for injection of radiographic contrast media or certain medicaments through the guiding catheter 10 or balloon catheter 16 during the operative procedure.

The typical coronary guiding catheter 10 comprises an elongate flexible plastic tube having preformed curves formed in the distal portion thereof to facilitate advancement of the distal portion of the catheter through the aortic arch and placement of the distal tip of the catheter within a desired coronary ostium. The curvatures formed in the distal portion of the guiding catheter will differ depending on which coronary artery the catheter is intended to access.

During the initial insertion of the coronary guiding catheter 10, it is common practice for the operator to grasp the exteriorized proximal portion of the catheter and to twist, torque, push and pull the catheter as necessary to guide the distal tip of the catheter into its desired position within the target coronary ostium. Accordingly, it is desirable that the guiding catheter 10 have sufficient structural rigidity to transmit torsional rotation of the catheter from the proximal end thereof to the distal end thereof. Moreover, during insertion of the guiding catheter 10, it is common for the distal tip of the catheter to rub against the luminal surfaces of the blood vessels through which it is advanced and to repeatedly probe or bump against the tissues surrounding the coronary ostia while the operator is endeavoring to guide and insert the distal tip of the catheter in the desired ostium.

Thus, it is desirable that the distal tip of the coronary guiding catheter 10 be sufficiently soft or flexible to avoid unnecessary trauma to the blood vessel

walls and/or coronary ostia during placement thereof.

The present invention is particularly applicable to coronary artery catheter 10 such as the guiding catheter illustrated in Figure 1 or standard coronary angiography catheters intended for insertion into a specific coronary artery for the purpose of infusing of radiographic contrast media directly into that coronary artery.

Figures 2, 2a and 5 show specific embodiments of coronary artery catheters in accordance with the present invention. Figures 4 and 6 show preferred intracorporeal operative placements of coronary artery catheters in accordance with the present invention.

In general, a coronary artery catheter of the present invention comprises an elongate catheter body 10 having a first proximal section 54, a second intermediate section 56 and a third distal tip section 58. The second intermediate section 56 is more flexible and less rigid than the first proximal section 54. Also, the second intermediate section 56 is of constant flexibility and rigidity throughout its entire length. The third distal tip section 58 is more flexible and less rigid than the second intermediate section 56. Thus, the catheter 10 is made up of at least three discrete regions of varying flexibility.

The difference in flexibility between the proximal 54, intermediate 56 and distal 58 regions of the catheter 10 may be accomplished by variations in material or variations in construction. For example, the body of the catheter 10 may be of substantially constant diameter along its entire

length but the proximal 54, intermediate 56 and distal 58 sections of the catheter may be formed of different materials having differing flexural properties. In such embodiments wherein the diameter of the catheter is constant but the flexural properties of the materials differ from region to region, it is preferable that the materials of which the proximal 54, intermediate 56 and distal 58 sections are formed be selected on the basis of the flexural properties set forth in Table I below:

TABLE I

Preferred Section Lengths and Material Properties for Catheters of Substantially Constant Diameter

Section of Catheter	Preferred Length (cm)	Preferred Flexural Modulus at 37°C psi (ASTM D-790)	Preferred Surface Hardness (Shore D)
First (Proximal)	Unspecified	20,000-40,000	55-65
Second (Intermediate)	1-10cm	15,000-35,000	45-60
Third (Distal)	0.1-0.5cm	2,000-10,000	25-45

In other embodiments of the invention, it may be desirable to form two or more adjacent sections of the catheter of the same material but to vary the diameter or mass of the catheter so as to result in differing overall flexibility from one section of the catheter to the next. For example, the proximal 54 and intermediate 56 sections

of the catheter may both be formed of the same material but the diameter of the intermediate 56 section of the catheter may be smaller than that of the proximal 54 section of the catheter, thereby causing the intermediate section 56 of the catheter to be more flexible and less rigid than the greater diameter proximal section 54. In such embodiment, the third distal section 58 of the catheter may be of the same diameter as the proximal section 54a but may be formed of a different material which is softer and more flexible than the remaining portion of the catheter.

Referring specifically to Figure 2, there is shown one presently preferred left coronary artery catheter 10a comprising a relatively rigid first or proximal section 54a which extends from the proximal end 50a of the catheter to the point indicated by broken line (a). A second or intermediate section 56a extends from line (a) to line (b). A third distal or "soft tip" section 58a extends distally beyond line (b).

The first or proximal section 54a of the catheter shown in Figure 2 comprises a substantially straight portion 64a and a secondary curve 62a formed therein. The secondary curve 62a is shaped to correspond to the anatomical configuration of the aortic arch.

A primary curve 60a is formed in the second intermediate section 56a of the catheter. Such primary curve 60a is shaped to facilitate passage of the distal tip 52a of the catheter 10a into the ostium of the left coronary artery as shown in Figure 4.

The first proximal section 54a of the catheter 10a is preferably formed of a flexible nylon material such as that marketed under the trademark PEBAX P6 (Atochimie, Courbevoie, Hauts-De-Sine, France). At 37°C PEBAX P6 has a Shore D durometer hardness of about 63 and a flexural modulus of about 30,000 psi. Optionally, reinforcement members such as stainless steel braiding may be formed within or around some or all of the proximal section 64a to enhance the torque transmitting capability and structural integrity of the first proximal section 54a.

The second intermediate section 56a of the catheter 10a is preferably formed of a nylon material such as PEBAX P5. At 37°C PEBAX P5 has a Shore D durometer hardness of about 55 and a flexural modulus of about 25,000 psi. Preferably, the second intermediate section 56a of the catheter 10a is devoid of any reinforcement or braiding as may optionally be incorporated in the first proximal section 54a thereof.

The third distal tip section 58a of the catheter 10a is preferably formed of PEBAX P3. At 37°C PEBAX P3 had a Shore D durometer hardness of about 35 and a flexural modulus 5,000 psi. Preferably the third distal tip portion 58a of the catheter is also devoid of any reinforcement or braiding and is sufficiently soft to avoid causing injury to the luminal surfaces of blood vessels and tissues surrounding the coronary ostia during insertion and placement of the catheter 10a.

A variant of the left coronary artery catheter of the present invention is shown in Figure 2a. The catheter shown in Figure 2a also has a first proximal section 54b, a second intermediate section 56b and a third distal tip section 58b. Also, the variant shown in Figure 2a has a primary curve 60b and a secondary curve 62b the same as that shown in the catheter of Figure 2. The variant shown in Figure 2a differs from the catheter shown in Figure 2, however, in that the second intermediate section 56b of the catheter 10b may be formed of material having the same hardness and flexural properties as that of the first proximal section 54b of the catheter but of a reduced mass or diameter relative to the proximal section 54b of the catheter 10b thereby causing the second intermediate section 56b of the catheter to be more pliable and flexible than the proximal portion 54b thereof.

In the variant shown in Figure 2a, it is preferable that both the first proximal section 54b and the second intermediate section 56b be formed of the same material, such as PEBAX P5. The third distal tip section 58b is preferably of the same diameter of the first proximal portion 62b and is formed of a different, more flexible material such as PEBAX P3.

Thus, it will be appreciated that the regionalized difference in flexibility between the first proximal section 54 and second intermediate section 56 of the catheter 10b shown in Figure 2a is accomplished by a reduction in mass or diameter of the catheter body while

the same regionalized variation in flexibility in the catheter 10a shown in Figure 2 is accomplished by forming the intermediate section 56a of a different more flexible material than the proximal section 54a.

Referring to Figure 5, a right coronary artery catheter 10c of the present invention also comprises a first proximal section 62c, a second intermediate section 56c and a third distal tip section 58c. As with the other embodiments of the coronary artery catheters of the present invention it is preferred that the first proximal section 62c be formed of a material having a Shore D durometer hardness of about 65 (e.g. PEBAX P6), that the second intermediate section 56c be formed of material having Shore D durometer hardness of about 45-55 (e.g. PEBAX P5) and that the third distal tip section 58c be formed of material having a Shore D durometer hardness of about 35 (e.g. PEBAX P3).

The right heart coronary artery catheter 10c, like the left heart coronary artery catheter 10a, 10b also incorporates a primary curve 60c and secondary curve 62c. The right heart coronary artery catheter 10c differs from the left heart coronary artery catheter 10a, 10b, however, in that primary curve 60c is directed toward to the right coronary artery rather than the left coronary artery as shown in Figure 6.

It will be appreciated that the right heart coronary artery catheter 10c of the present invention may be of essentially the same construction and design as the left

heart coronary artery catheter 10a 10b except that the primary curve 60c of the right coronary artery catheter will differ in direction and shape from primary curve 60a, 60b of the left coronary artery catheter.

Irrespective of whether the coronary artery catheter 10 is shaped for insertion into the left coronary artery (10a, 10b) or right coronary artery (10c) it is preferable that the third distal portion 58 and the second intermediate portion 56 be of lengths which will facilitate placement and residence of those portions of the catheter within the desired regions of the human vasculature. In adult coronary artery catheters 10 of the present invention, it is preferable that the length l1 of the third distal tip section 58 be 1-5 millimeters and preferably about 3 millimeters. Also, it is preferable that the length l2 of the second intermediate section 56 be 1-10 centimeters and preferably about 4 centimeters. The length of the first proximal section 54 and any additional segments or sections of the catheter may vary in size depending on the overall desired length of the catheter.

In adult coronary artery catheters 10 of the present invention, such catheters are generally sized such that the outer diameter of the catheter is 11-12 French and the overall length of the catheter is approximately 100 centimeters. Other sizes are appropriate for pediatric use or other applications.

The length of the third distal tip section 58 and the length of the second intermediate section 56 of the

coronary artery catheters 10 of the present invention are specifically selected to correspond to the regions of the aortic arch and coronary ostium wherein those sections of the catheter 10 normally reside during in situ placement. The normal in situ operating positions of the left 10a and right 10c coronary artery catheters of the present invention are shown in Figures 4 and 6 respectively.

Referring to Figure 4, a left coronary artery guiding catheter 10a of the present invention is typically inserted into a femoral artery 44 and advanced in a retrograde fashion through the descending aorta 46, through the aortic arch 82 and down the ascending aorta 84 to a position where the distal tip section 58a of the catheter 10a becomes inserted into the ostium 92 of the left coronary artery 88. When so positioned, the secondary curve 62a of the catheter 10a resides within the arch of the aorta 82 without exerting excessive pressure or excessive rubbing against the walls of the aortic arch 82.

In a similar fashion, as shown in Figure 6, the distal tip portion 58c and the second intermediate portion 56c of the right heart catheter are specifically sized and configured such that, when the distal tip section 58c of the catheter 10c is operatively inserted into the ostium of the right coronary artery 86, the secondary curve 62c of the catheter 10c will reside within the aortic arch 82c without exerting excessive pressure or excessively rubbing against the walls of the aortic arch 82.

It will be appreciated that the invention has been described herein by making specific reference to certain preferred embodiments of coronary artery catheters. Many other embodiments of the invention may be prepared without departing from the spirit and scope of the invention herein disclosed. For example, the catheters of the present invention may be sized and configured for use for insertion and positioning in the renal artery, pulmonary artery, arteries of the cerebrovascular circulation, etc.

Additionally, it will be appreciated that various modifications, additions and alterations may be made to the preferred embodiments which are shown and described herein. Accordingly, it is intended that all such additional embodiments and modifications, additions and alterations to the herein described embodiments be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A cardiovascular catheter comprising:

an elongate tubular catheter body having a distal end, a proximal end and at least one hollow lumen extending longitudinally therethrough;

said tubular catheter body being divided into at least three sections comprising:

(a) a first proximal section having a proximal end and a distal end;

(b) a second intermediate section having a proximal end and a distal end, the proximal end of said second intermediate section being joined to the distal end of said first proximal section, said second intermediate section being of consistent rigidity along its length, and the rigidity of said second intermediate section being less than that of said first proximal section; and

(c) a third distal tip section having a proximal end and a distal end, the proximal end of said distal tip section being joined to the distal end of said intermediate section and extending therefrom to form the distal terminus of the catheter, the rigidity of said third distal tip section being less than that of said second intermediate section.

2. The cardiovascular catheter of Claim 1 wherein said second intermediate section is 1-10 centimeters in

length.

3. The cardiovascular catheter of Claim 1 wherein said second intermediate section is about 4 centimeters in length.

4. The cardiovascular catheter of Claim 1 wherein said third distal tip section is 0.1-0.5 centimeters in length.

5. The cardiovascular catheter of Claim 1 wherein said third distal section is about 0.3 centimeters in length.

6. The cardiovascular catheter of Claim 1 wherein said first proximal section is comprised of material having a Shore D surface in the range of 55-75.

7. The cardiovascular catheter of Claim 1 wherein said second intermediate section is comprised of material having a Shore D surface in the range of 40-60.

8. The cardiovascular catheter of Claim 1 wherein said third distal section is comprised of material having a Shore D surface in the range of 25-45.

9. The cardiovascular catheter of Claim 1 wherein the catheter is of constant diameter and wherein the first proximal, second intermediate and third distal sections of the catheter are formed of different materials such that:

the material of which the first proximal section is formed has a flexural modulus of 20,000-40,000 psi at 37°C;

the material of which the second intermediate

section is formed has a flexural modulus of 15,000-35,000 psi at 37°C; and

the material of which the third distal section is formed has a flexural modulus of 2,000-10,000 psi at 37°C.

10. The cardiovascular catheter of Claim 1 wherein the catheter is of constant diameter and wherein the first proximal, second intermediate and third distal sections of the catheter are formed of different materials such that:

the material of which the first proximal section is formed has a flexural modulus of about 30,000 psi at 37°C;

the material of which the second intermediate section is formed has a flexural modulus of about 25,000 psi at 37°C; and

the material of which the third distal section is formed has a flexural modulus of about 5,000 psi at 37°C.

11. The cardiovascular catheter of Claim 1 wherein the catheter comprises a continuous flexible tube which is devoid of secondary reinforcement materials.

12. The cardiovascular catheter of Claim 1 wherein the catheter comprises a continuous flexible tube which is devoid of braided steel reinforcement members.

13. The cardiovascular catheter of Claim 1 further comprising:

a braided steel torsional reinforcement member positioned in at least a portion of the first proximal

section of the catheter to facilitate transmission of rotational torque through that portion of the first proximal section of the catheter.

14. The cardiovascular catheter of Claim 1 wherein the first proximal and second intermediate sections are formed of the same material but wherein the diameter of the second intermediate section is smaller than the diameter of the first proximal section, thereby rendering the second intermediate section more flexible and less rigid than said first proximal section.

15. The cardiovascular catheter of Claim 12 wherein the third distal section is of approximately the same diameter as the first proximal section but wherein the third distal section is formed of a material which is more flexible and less rigid than the material of which the first proximal and second intermediate sections are formed.

16. The cardiovascular catheter of Claim 1 further comprising:

a primary curve formed in the second intermediate section of the catheter to direct and facilitate insertion of the distal end of the catheter into a desired coronary artery upon retrograde advancement of the catheter through the aorta.

17. The cardiovascular catheter of Claim 1 further comprising:

a secondary curve formed in a portion of the first proximal section of the catheter to conform the

shape of that portion of the catheter to the aortic arch.

18. A coronary artery catheter comprising an elongate tubular catheter body having a distal end, a proximal end and at least one hollow lumen extending longitudinally therethrough, said catheter body being divided into at least three sections comprising:

a first proximal section having a proximal end and a distal end, said first proximal section being formed of material having a flexural modulus of 20,000-40,000 psi at 37°C;

a second intermediate section having a proximal end and a distal end, the proximal end of said intermediate section being joined to the distal end of said first proximal section, said second intermediate section being of consistent rigidity along its length and the rigidity of said second intermediate section being less than that of said first proximal section, said second intermediate section being formed of a material having a flexural modulus of 15,000-30,000 psi at 37°C;

a third distal tip section having a proximal end and a distal end, the proximal end of said distal tip section being attached to the distal end of said intermediate section and extending therefrom to form the distal terminus of the catheter, said distal tip section being formed of a material having a flexural modulus of 2,000-10,000 psi at 37°C;

a primary curve formed in the second intermediate section to direct and facilitate insertion of the distal end of the catheter body into a desired coronary artery upon retrograde advancement of the catheter through the aorta; and

a secondary curve formed in a portion of the first proximal section of the catheter to conform that portion of the catheter to the anatomical configuration of the aortic arch.

19. The coronary artery catheter of Claim 18 wherein said second intermediate section is 1-10 centimeters in length and said third distal tip section is 1-5 centimeters in length.

20. The coronary artery catheter of Claim 18 wherein said second intermediate section is approximately 4 centimeters in length and the third distal tip section is approximately 0.3 centimeters in length.

21. The coronary artery catheter of Claim 18 wherein the first proximal section is formed of material having a flexural modulus of approximately 30,000, the second intermediate section is formed of material having a flexural modulus of approximately 25,000 and the third distal tip section is formed of material having a flexural modulus of approximately 5,000.

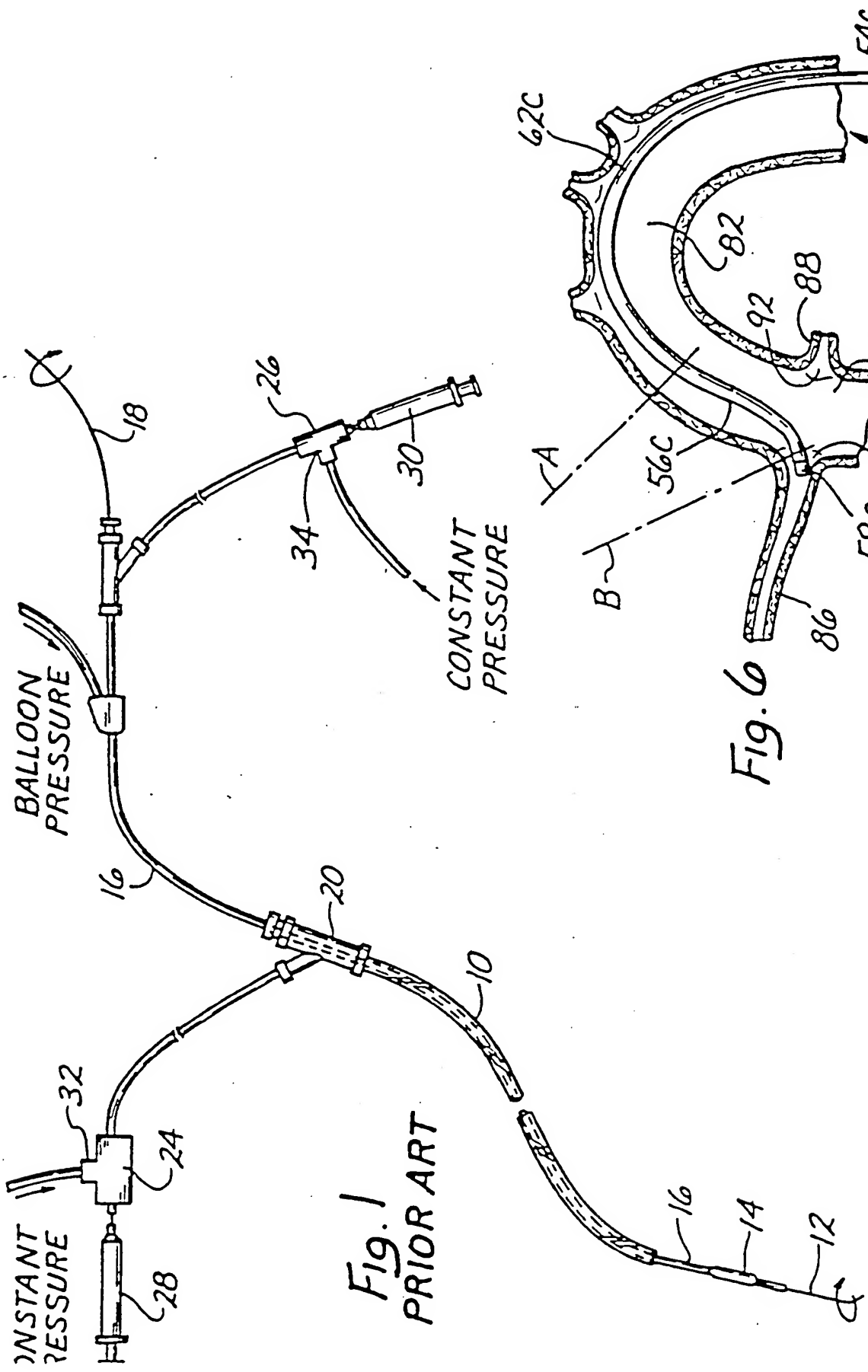

Fig. 1
PRIOR ART

Fig. 6

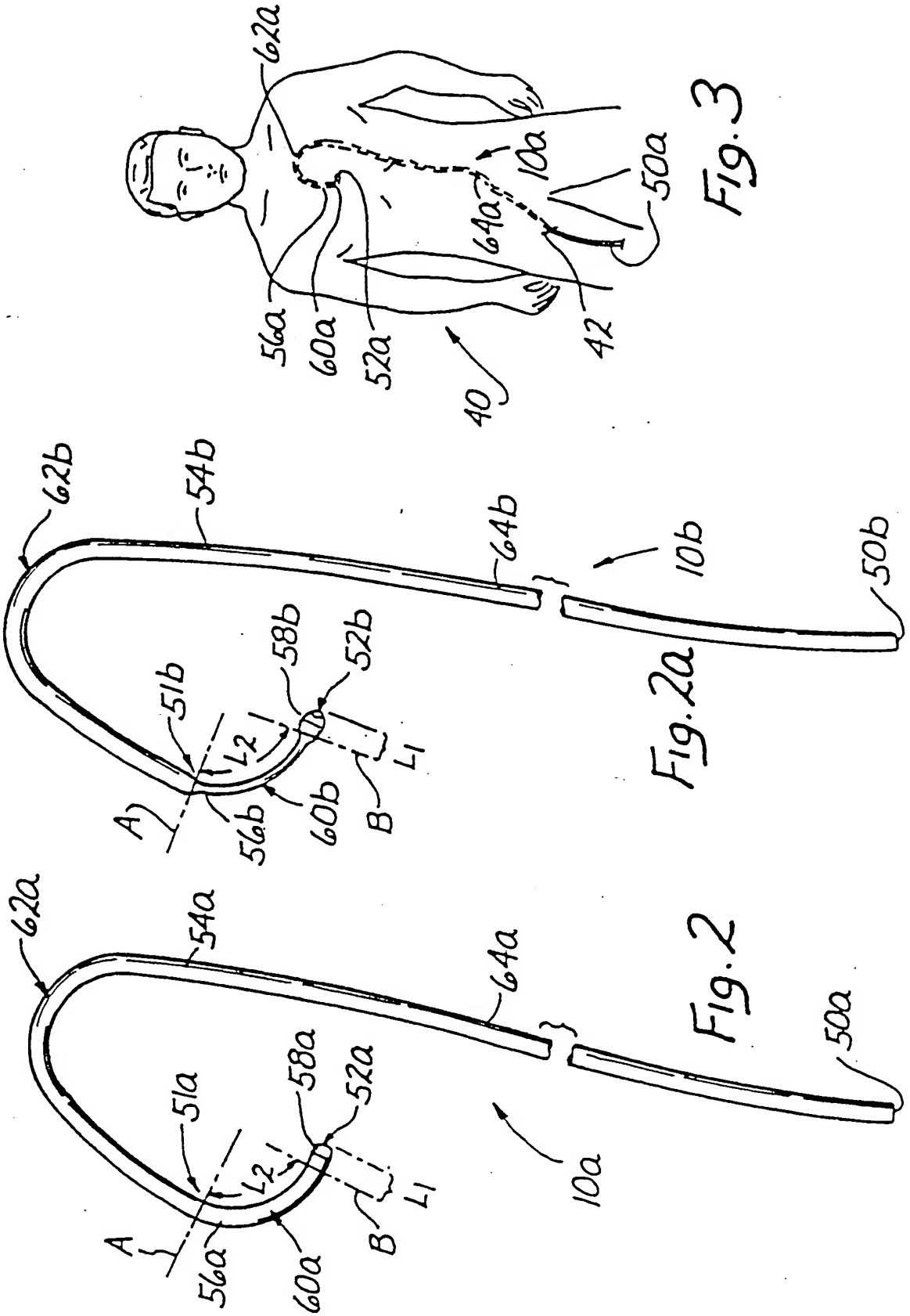

Fig. 3

Fig. 2a

Fig. 2

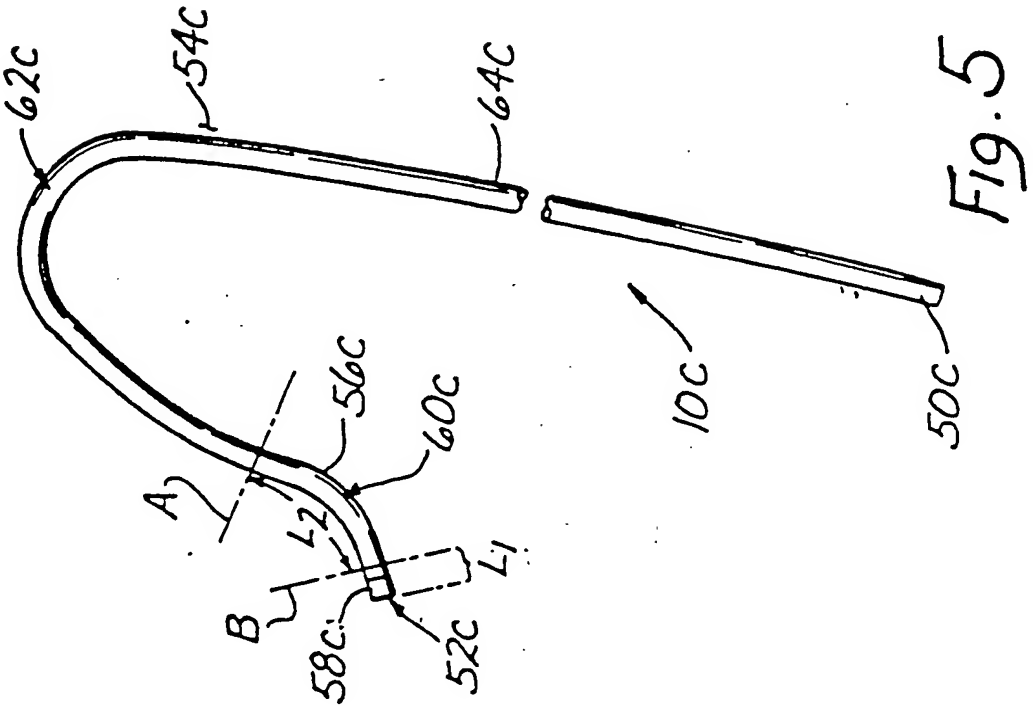
62c
54c
64c
56c
60c
A
L2
L1
B
58c
52c
10c
50c

Fig. 5

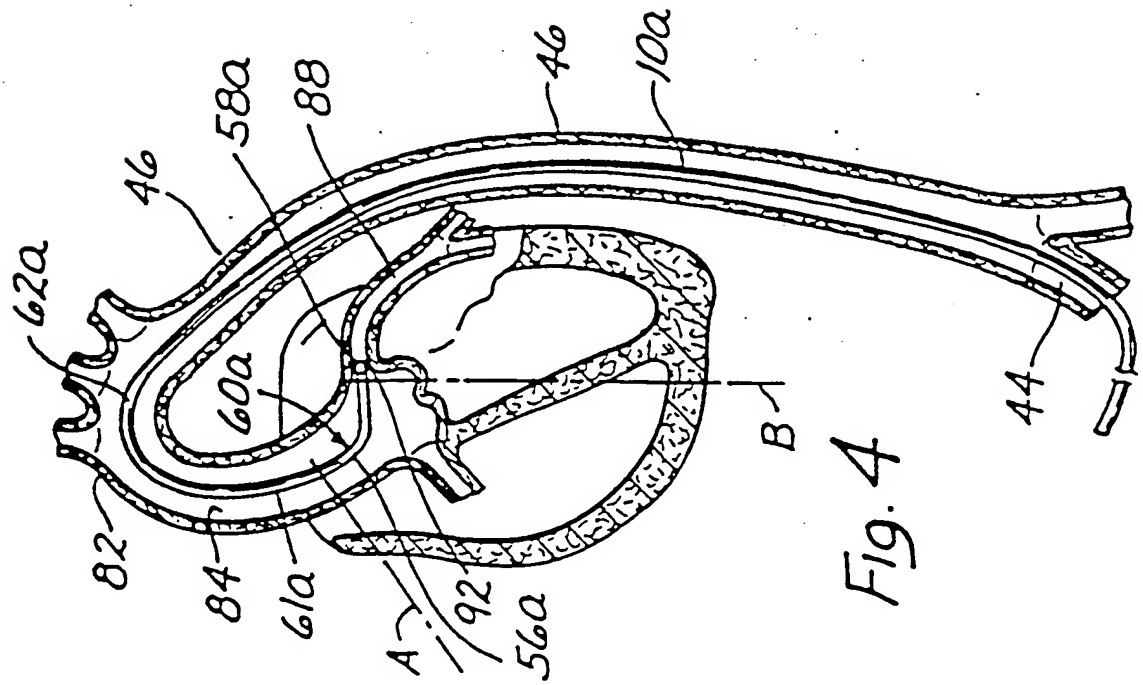
46
10a
58a
88
62a
60a
B
44
82
84
61a
92
A
56a

Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 92/01590

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all:)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M25/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category*	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X Y	DE,A,2 140 755 (SHERWOOD MEDICAL INDUSTRIES INC.) 22 February 1973 see page 6, paragraph 2 -paragraph 3; figure 2	1-12,15, 17 18-21
Y A	EP,A,0 256 478 (DANFORTH) 24 February 1988 see abstract; figures	18-21 16-17
A	WO,A,9 010 466 (ARROW INTERNATIONAL INVESTMENT CORP.) 20 September 1990 see page 7, line 13 - page 8, line 23; figure 3	1-21
A A,P	WO,A,9 011 793 (MITSUBISHI CABLE INDUSTRIES, LTD.) 18 October 1990 see abstract; figures 1-4 & EP,A,0 420 993 (MITSUBISHI CABLE INDUSTRIES) 10 April 1991	13
A	US,A,4 983 169 (FURUKAWA) 8 January 1991 see column 4, line 33 - line 46; figure 4	14

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* Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
10 JULY 1992	28.07.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	US,A,4 323 071 (SIMPSON ET AL.) 6 April 1982 see column 4, line 15 - line 22; figure 1	16-21

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9201590 SA 58240

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 10/07/92
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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